

REMARKS

Reconsideration of this application in view of the above amendment and following remarks is respectfully requested.

The undersigned is now the attorney of record for this application. Duly executed Revocation and Substitute Powers of Attorney from the current assignee, Research Development Foundation, to the undersigned were submitted on September 19, 2003 and acknowledged in the Notice of Acceptance of Power of Attorney mailed October 10, 2003.

A replacement sheet of drawings is presented herewith for approval. This sheet provides the correct Figure 8, which was previously filed in the priority provisional application (U.S. Patent Application No. 60/273,969), and for which a duplicate of Figure 6 was inadvertently provided at the time of filing the instant application. Such an amendment at the present time is proper since the correct Figure 6 was submitted in the priority provisional application USSN 60/273,969, which was incorporated by reference in its entirety in this application.

Claims 1 and 4-8 are now pending. Claim 6 has been amended to more clearly recite certain aspects of the invention (*i.e.*, a host cell “comprising” as opposed to “transfected with”). Support for this amendment may be found throughout the specification as originally filed and does not constitute addition of new matter.

Claims 1 and 4-7 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent Application Publication No. 2003/0165807 to Isfort *et al.* (hereinafter “Isfort *et al.*”), while claim 8 stands rejected under 35 U.S.C. §103(a) as obvious over Isfort *et al.* More specifically, the Examiner asserts that Isfort *et al.* disclose a sequence of urocortin II (SEQ ID NO:43; page 4, Table I), which is 100% identical to the amino acid sequence of SEQ ID NO:11 of the claimed invention and which, therefore, anticipates claim 1. The Examiner further asserts that Isfort *et al.* indicate that urocortin II was cloned from *Mus musculus* and, therefore, meets the limitations of claims 4-7. In addition, the Examiner is of the opinion that although Isfort *et al.* do not expressly disclose transfection of *E. coli* cells with a vector comprising DNA encoding urocortin II, it would have been *prima facie* obvious to a person of ordinary skill to modify the disclosure of Isfort *et al.* and propagate the DNA encoding urocortin II in *E. coli*.

Applicants respectfully traverse these rejections for the reasons set forth below.

As an initial matter, Isfort *et al.* was not published before invention of the claimed subject matter by Applicants and, thus, cannot serve as a §102(e) reference for purpose of novelty or under §103(a) with regard to obviousness. Rather, Applicants possessed the presently claimed invention at least as early as February 27, 2001, which is prior to the March 6, 2001 priority filing date of Isfort *et al.* To evidence this date, Applicants submit herewith a 37 C.F.R. § 1.131 (“Rule 131”) Declaration by one of the co-inventors, Dr. Wylie Vale.

In his Declaration, Dr. Vale at ¶¶ 3-5 discusses an article entitled, “Urocortin II: A member of the corticotropin-releasing factor (CRF) neuropeptide family that is selectively bound by type 2 CRF receptors,” published in *Proc. Natl. Acad. Sci.* 98:2843-2848 on February 27, 2001 (hereinafter referred to as “Reyes *et al.*”). Reyes *et al.* describes the polypeptide sequence of murine urocortin II, including the peptide coding region (Fig. 1). Accordingly, Reyes *et al.* antedates Isfort *et al.* by establishing actual reduction to practice of the claimed invention at least as early as its publication date of February 27, 2001.

In addition, the above-mentioned declaration by Dr. Vale also establishes that the Reyes *et al.* article represents the work of the Applicants (since such a showing is typically presented by way of a 37 C.F.R. §1.132 (“Rule 132”) Declaration, the attached Declaration by Dr. Vale is entitled “Combined Rule 131/132 Declaration” and, hereinafter, simply referred to as “the Dr. Vale Declaration”). More specifically, the Dr. Vale Declaration, at ¶ 6, establishes that the work set forth in Reyes *et al.* was the work of the Applicants (*i.e.*, co-inventors W. W. Vale, T. M. Reyes, P. E. Sawchenko, J. Rivier, K. Lewis, J. B. Hogenesch, J. Vaughan and M. H. Perrin) and that the contribution of the additionally-name authors (*i.e.*, K. Kunitake, C. A. Arias and J. Gulyas) did not arise to an inventive level, but instead was work performed under the direction or supervision of one or more of the co-inventors. See *In re Katz*, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982). Therefore, although Reyes *et al.* predates the priority filing date awarded for the pending claims, it does not constitute a §102(a) reference (nor can it serve in the context of a §102(a)/103(a) rejection), since it does not represent the work of another.

Accordingly, in view of the above remarks and the Dr. Vale Declaration submitted herewith, Applicants respectfully submit that Isfort *et al.* has been antedated and request that both the novelty and obviousness rejections premised thereon be withdrawn.

Lastly, Applicants note that an Information Disclosure Statement is submitted with the present amendment. Applicants wish to specifically bring to the Examiner's attention, in addition to Reyes *et al.*, the following documents, which are provided with the accompanying Information Disclosure Statement:

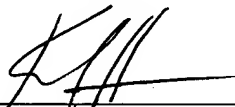
- (1) WO 02/34934 to Stanford: This PCT was published on May 2, 2002 but did not designate the United States and, thus, is not available as prior art under §102(e)(1).
- (2) U.S.S.N. 09/682,706 to Stanford: This U.S. application was filed on October 9, 2001, published on June 27, 2002, and claims priority to provisional application Nos. 60/244,128, filed October 26, 2000, and 60/276,615, filed March 15, 2001. This application is not available as prior art under 35 U.S.C. §102(e), since the priority provisional application No. 60/244,128 fails to disclose mouse urocortin II sequences, and the priority provisional application No. 60/276,615 was filed after the acknowledged priority date of the instant application of March 7, 2001. For the Examiner's convenience, copies of the priority provisional applications are also provided.
- (3) GenBank Database Accession No. AF331517, March 6, 2001. The identification and submission of this sequence is described in Reyes *et al.* Accordingly, this sequence also represents the work of Applicants and, therefore, does not constitute a §102(a) reference.

Applicants note that the other references listed on the accompanying Form PTO-1449 do not disclose the claimed mouse urocortin II sequences and/or were not published prior to the instant application's acknowledged priority date of March 7, 2001, and, therefore, do not constitute prior art under 35 U.S.C. § 102.

Applicants respectfully submit that claims 1 and 4-8 are in condition for allowance. A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention, the Examiner is requested to contact the undersigned at (206) 622-4900.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



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Enclosures:

1 Sheet of Drawings (Figure 8)  
Combined Rule 131/132 Declaration of Wylie Walker Vale, Jr., Ph.D.  
*Reyes et al., Proc. Natl. Acad. Sci.* 98:2843-2848 (February 27, 2001)

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